



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 16, 2020

Micah T. Reynolds
Senior Regulatory Consultant
Alpha Tech Pet, Inc.
25 Porter Road, Suite 210
Littleton, MA 01460

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Kennelsol
EPA Registration Number: 62472-1
Application Date: March 30, 2020
Decision Number: 561261

Dear Mr. Reynolds:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroups are small non-enveloped, large non-enveloped, and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Picornavirus and Canine Parvovirus are suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label

***PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed, inhaled or absorbed through the skin. Avoid breathing spray mist. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), protective clothing and protective gloves (rubber or chemical resistant). Wash thoroughly with soap and water after handling and before eating drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15 – 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

(Note to reviewer: If container size is 5 gallons or greater, the following Environmental Hazards statements will be used:)

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. This pesticide is toxic to fish, aquatic invertebrates, oysters, and shrimp. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

KENNELSOL

Germicidal Detergent & Deodorant

A multi-purpose germicidal detergent and deodorant effective in hard waters up to 400 ppm hard water (calculated as CaCO₃) plus 5 % organic serum. Disinfects, cleans, and deodorizes in one labor saving step.

For use in kennels, pet shops, tack shops, veterinary clinics, animal life science laboratories, breeding & grooming establishments, schools, colleges, equine farms, airports, hotels & motels. For use in households.

Active Ingredients:

Didecyl dimethyl ammonium chloride 2.535%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)

dimethyl benzyl ammonium chloride 1.690%

Other Ingredients:..... 95.775%

Total 100.000%

KEEP OUT OF REACH OF CHILDREN

DANGER

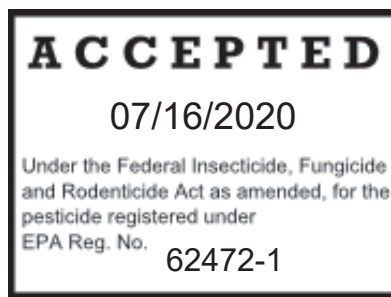
See (right) (left) (side) (back) (bottom of label) panel
for (additional) (Precautionary Statements) (and)
(Directions for Use) *

EPA Reg. No. 62472-1

EPA Est. No. *(insert Est. No. here)*

NET CONTENTS *(insert container size here)*

Alpha Tech Pet, Inc.
25 Porter Road, Suite 210
Littleton, MA 01460



Bactericidal against the following pathogenic bacteria according to the AOAC Use-Dilution Test method, current edition, modified in the presence of 400 ppm synthetic hard water (calculated as CaCO_3) plus 5% organic serum:

Proteus vulgaris
Bordetella bronchiseptica
Serratia marcescens
Escherichia coli
Staphylococcus aureus (antibiotic resistant)
Fusobacterium necrophorum
Klebsiella pneumoniae (antibiotic resistant)
Streptococcus pyogenes
Proteus mirabilis
Salmonella enterica
Salmonella typhimurium
Escherichia coli (antibiotic resistant)
Shigella sonnei
Staphylococcus epidermidis (antibiotic resistant)
Enterobacter cloacae
Pasteurella multocida

Staphylococcus aureus
Salmonella typhi
Chlamydia psittaci
Shigella flexneri
Enterobacter aerogenes
Streptococcus faecalis (antibiotic resistant)
Klebsiella pneumoniae
Streptococcus faecalis

Fungicidal against Trichophyton mentagrophytes and Candida albicans according to the AOAC fungicidal test, modified in the presence of 400 ppm hard water (calculated as CaCO_3) plus 5% organic serum.

Virucidal against *Canine parvovirus, Canine distemper, Feline leukemia, Feline panleukopenia, Feline picornavirus, ***HIV-1 (AIDS virus), Influenza A/Hong Kong, Herpes simplex type 1, Herpes simplex type 2, Vaccinia, Rubella, Adenovirus type 4, Rabies, Porcine parvovirus, Pseudorabies, Infectious bovine rhinotracheitis, Infectious bronchitis (Avian IBV), **Avian Influenza A (H3N2) virus (Avian Reassortant) (ATCC VR-2072), and **Avian Influenza A (H5N1) virus according to the virucidal qualification, modified in the presence of 400 ppm hard water (calculated as CaCO_3) plus 5 % organic serum.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

DIRECTIONS FOR DISINFECTING: (Bactericidal, Fungicidal, Virucidal)

For use on hard, non-porous non-food contact surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, and plastic surfaces. Remove gross filth and heavy soil deposits then thoroughly wet surfaces. Use 2 ounces per gallon of water (8 ounces per gallon against canine parvovirus and Porcine parvovirus) for a minimum contact time of 10 minutes in a single application. Can be applied with a cloth, mop, or sponge, as well as by coarse spray or soaking. The use solution is prepared fresh for each use then discarded. Rinsing is not necessary unless floors are to be waxed or polished.

FUNGICIDAL DIRECTIONS:

For use in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities follow disinfection directions.

MILDEWSTATIC INSTRUCTIONS:

Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, non-porous surfaces such as walls, floors, and table tops. Apply solution (2 ounces per gallon of water) with a cloth, mop, sponge or coarse spray making sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

VETERINARY CLINICS / ANIMAL CARE / ANIMAL LIFE SCIENCE LABORATORIES / ZOOS / PET SHOP / KENNELS / BREEDING AND GROOMING ESTABLISHMENTS / EQUINE FARMS DISINFECTION DIRECTIONS:

For disinfecting the following hard nonporous surfaces: equipment used for animal food or water, utensils, instruments, cages, kennels, stables, catteries, etc. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with a solution of 2 oz of KennelSol per gallon of water (or equivalent dilution) (8 ounces per gallon against Canine parvovirus or Porcine parvovirus), using a cloth, mop, sponge, spray, or soaking for a period of 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

***FOR CANINE PARVOVIRUS (AND PORCINE PARVOVIRUS) ACTIVITY:**

KennelSol is effective against Canine Parvovirus (and Porcine parvovirus) at 8 oz. per gallon. Follow Veterinary Practice / Animal Care / Animal Laboratory / Zoos / Pet Shop / Kennels Disinfection Directions.

****SPECIAL INSTRUCTIONS FOR INACTIVATING**

AVIAN INFLUENZA: Remove all poultry and feeds from premises, trucks, coops, and crates. Remove all litter and droppings from floors, walls, and surfaces of facilities occupied or traversed by poultry. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with soap or detergent and rinse with water. Saturate surfaces with the disinfecting solution (2 oz per gallon of water) (660 ppm active quat) (equivalent use dilution) for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels, and scrapers used in removing litter and manure. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

*****KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY**

FLUIDS in healthcare settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surface/object likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) OF SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS.

Personal Protection:

Disposable latex or vinyl gloves, gowns, face masks, and eye coverings as appropriate, must be worn during all cleaning of body fluids, blood, and decontamination procedures.

Cleaning Procedures:

Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of disinfectant.

Contact Time:

Effective against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of a moderate

amount of organic soil (5% blood serum) when used at a 1:64 dilution (providing 660 ppm of active quaternary) in 400 ppm CaCO₃ hard water for a contact time of 4 minutes at room temperature (20-25°C). Use a ten (10) minute contact time for disinfection against all other bacteria, fungi, and viruses claimed (listed on labeling).

Disposal of Infectious Materials:

Blood and other body fluids must be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

(Note for reviewer: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:)

This product is not to be used as a terminal sterilant / high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

(or)

This product is not for use on medical device surfaces.

(Note to reviewer: the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL

(containers for household/residential use)

PESTICIDE STORAGE: Store in original container in areas inaccessible to children.

PESTICIDE DISPOSAL AND CONTAINER

HANDLING: Nonrefillable container. Do not reuse or refill this container. Wrap (container) and put in trash or offer for recycling if available.

(Note to reviewer: the following Storage and Disposal directions will be used:)

STORAGE AND DISPOSAL

(containers for commercial, industrial, and institutional use)

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE

Store in original container in areas inaccessible to children. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your local State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING

(For containers 5 gallons or less):

(Plastic containers:) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(For containers greater than 5 gallons):

(Plastic containers:) Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

For use in: Kennels, pet shops, veterinary clinics, animal life science laboratories, breeding establishments, grooming establishments, schools, colleges, federally inspected meat and poultry plants, equine farms, tack shops, zoos, poultry farms, turkey farms, dairy farms, hog farms, and households. Disinfects, cleans, and deodorizes the following hard nonporous non-food contact inanimate surfaces: floors, walls, non-medical metal surfaces, non-medical stainless steel

surfaces, glazed porcelain, plastic surfaces (such as polypropylene, polystyrene, etc.).

Recommended for use in: Federally inspected meat and poultry plants as a disinfectant agent for use in all departments. Food products and packaging materials must be removed from the room or carefully protected. Use product in accordance with its label. All surfaces must be thoroughly rinsed with potable water.

Claims Against Emerging Viral Pathogens

This product qualifies for emerging viral pathogen claims per the EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels" when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make the claims against certain emerging viral pathogens from the following viral category[ies]:

- Enveloped Viruses
- Large Non-Enveloped Viruses
- Small Non-Enveloped Viruses

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Feline Picornavirus
Large, non-enveloped virus	Feline Picornavirus
Small, non-enveloped virus	Canine Parvovirus

(Acceptable claim language:)

[Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [insert name of emerging virus] when used in accordance with the directions for use against Feline Picornavirus and Canine Parvovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. [Product Name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Feline Picornavirus and Canine Parvovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

(Note to reviewer: Language in () is optional or interchangeable)